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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/630,383	04/10/1996	PHILIPPE POULETTY	A-55320-2/BI	3596

7590

09/24/2002

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EXAMINER
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SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/24/2002

40

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
08/630,383

Applicant(s)

Pouletty et al.

Examiner  
Ron Schwadron, Ph.D.

Art Unit  
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 14-20 is/are pending in the application.
- 4a) Of the above, claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-17, 19, and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

1. Applicant's election of the species alpha galactosyl antigen in Paper No. 39 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 39.

3. Claims 14-17,19,20 are under consideration.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14-17,19,20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "non-cytotoxic" in claims 14,19. None of the passages of the specification to which applicant refers discloses "non-cytotoxic" conjugates. In addition, to the extent that "non-cytotoxic" could be interpreted as meaning lacking cytotoxicity under any circumstances, all of the conjugates disclosed in the specification are "cytotoxic" in the presence of the appropriate effector mechanism (eg. anti-alpha gal antibodies, etc). It appears that applicant intends to refer to a conjugate that does not exhibit cytotoxicity in the absence of other effector mechanisms. There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

6. Claims 14-17,19,20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 19 are indefinite in the recitation of "non-cytotoxic conjugate" because it is unclear what this means or encompasses. Said term is not defined in the specification and has no art recognized meaning. It is unclear if said term refers to a conjugate that is only not cytotoxic in the absence of other effector mechanisms (eg. antiGal antibodies) or whether it encompasses a conjugate that would be not cytotoxic under any conditions (eg. in the presence of other effector molecules).

7. Regarding priority for the claimed invention and the application of prior art, the claimed invention using folate is not disclosed in the parent applications to which priority is claimed and therefore the priority date for application of prior art is the filing date of the instant application.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application under section 122(b) only if the international application designating the United States was published Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

9. Claims 14-17,19,20 are rejected under 35 U.S.C. 102(e) as being by Kranz et al.(US Patent 5,547,668) as evidenced by Borrebaeck et al.

Kranz et al. teach therapeutic conjugates containing folate covalently joined to a murine antibody (see column 4, third paragraph and column 7). Borrebaeck et al. disclose that the art recognized that murine antibodies contain alpha Gal which is bound by human anti alpha Gal antibodies(see page 477, second column). Thus, it is an inherent property of the conjugates taught by Kranz et al. that they contain the alpha Gal/ alpha galactosyl epitope. The conjugates are "non-cytotoxic" to the extent that they are not cytotoxic in the absence

of exogenous effector mechanisms.

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-7939.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON.  
PRIMARY EXAMINER  
GROUP 1600 (600

Ron Schwadron, Ph.D.  
Primary Examiner  
Art Unit 1644